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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/260,536	06/16/1994	ROBERT M. LORENCE	57704	4057

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/260,536	LORENCE ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *332-366* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *332-366* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. To allow entry of rejection(s) set forth below, the following office action is non-final.

Claims status

2. Claims 356-366 are added. Claims 1-331 are cancelled. Claims 332-366 are pending and currently under examination.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 332-333 (with regard to melanoma), 335, 338-339, 343-344(with regard to melanoma), 346, 349-350 are rejected under 35 U.S.C. 102(b) as being anticipated by Cassel et al. (Cassel et al. A ten-year follow-up on stage II malignant melanoma patients treated postsurgically with Newcastle disease virus oncolysate. Med Oncol Tumor Pharmacother 9 (4): 169-71, 1992.).

The claims are directed at a method of treating cancer in a mammal having a tumor comprising administering systemically to said mammal a live Newcastle Disease Virus (NDV) in an amount sufficient to cause tumor regression. A claim further limits the tumor to melanoma. Other claims limit the virus to strain 73-T, and that the administration occur in multiple doses.

Cassel et al. teaches the systemic administration of a viral oncolysate, in more than one dose, to patients having a tumor, specifically melanoma. The viral oncolysate of Cassel et al. comprises live Newcastle Disease Virus, NDV. The viral strain that Cassel et al. teaches is 73-T, as evidenced by Cassel et al. (Cassel et al. Newcastle Disease virus as an antineoplastic agent. Cancer 18: 863-8, 1965; wherein Cassel et al. teaches how to make the 73-T variant of Newcastle disease virus). The method of administration used by Cassel et al. is subcutaneous administration, which is a systemic mode of administration. Cassel et al. notes that the administration of the viral oncolysate enhances the recurrence-free interval of the tumor in patients that received the viral oncolysate treatment. Thus, the amount of viral oncolysate administered by Cassel et al. is an amount effective to cause tumor regression. In the instant, the teaching of Cassel et al. is the same as that of the claimed invention. Ergo, Cassel et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 333 (with the exception of melanoma), 334, 366, 344 (with the exception of melanoma), 345, 347, 356, 357, 359-360 and 365-366 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cassel et al. (Cassel et al. A ten-year follow-up on

stage II malignant melanoma patients treated postsurgically with Newcastle disease virus oncolysate. Med Oncol Tumor Pharmacother 9 (4): 169-71, 1992.)

The claims limit the tumor to colon adenocarcinoma, neuroblastoma, cervical cancer; and selected from the group consisting of lung carcinoma, breast carcinoma, prostate carcinoma, endometrial carcinoma, ovarian carcinoma, bladder carcinoma, Wilm's tumor, fibrosarcoma, osteosarcoma, synovial sarconoma, and glioblastomas.

Cassel et al. does not teach administration of the viral oncolysate to a patient group that have various tumors, such as: colon adenocarcinoma, neuroblastoma, cervical cancer; and selected from the group consisting of lung carcinoma, breast carcinoma, prostate carcinoma, endometrial carcinoma, ovarian carcinoma, bladder carcinoma, Wilm's tumor, fibrosarcoma, osteosarcoma, synovial sarconoma, and glioblastomas.

However, through laboratory studies, it is well established that viral oncolysates can be highly effective immunizing agents against challenge by the autogenous tumors, first full paragraph, Introduction section, page 169 of Cassel et al. Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to administer viral oncolysate to different patient groups. One of ordinary skill in the art at the time the invention was made would be motivated to administer viral oncolysate to different patient groups to treat said groups of their specific ailment.

One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because it is well established that viral oncolysates can be highly effective immunizing agents against challenge by the

autogenous tumors, which is further exemplified by the teaching of Cassel et al.--who successfully used viral oncolysate, wherein the virus is NDV, to treat patients having a tumor.

Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

7. Claims 340-341, 353-356 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cassel et al. in view of Cohen et al. (U.S. Patent No. 5739107).

The claims limit the administration to intravenous and intrapertoneal methods of administration.

As noted above, Cassel et al. uses the subcutaneous method of administration. Cassel et al. does not teach intravenous or intrapertoneal methods of administration. However, Cohen et al. teaches of other means of systemic administration, which includes subcutaneous, intravenous, and intraperitoneal method of administration—lines 55-57, column 5, and lines 53-63, column 21. Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to substitute one art recognized method of administration with another with the expectation that the substituted method would induce the same affect as the other method(s).

Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

8. Claims 337, 348 and 361-362 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cassel et al. in view of Hanson et al. (Hanson et al. Identification of vaccine strains of Newcastle disease virus. Science, July 1955, Vol. 122, p. 156-157.)

The claims limit the virus to the MK107 variant of NDV.

As noted above, Cassel et al. teaches the 73-T variant of NDV. Cassel et al. does not teach the MK107 variant of NDV.

However, Hanson et al. teaches the MK107 variant of NDV, Table 1.

In the instant, Cassel et al. notes that NDV is a potent inducer of interferon in humans and promotes the formation of tumor necrosis factor, see bridging paragraph, pages 170-171. The characteristics noted by Cassel et al. are intrinsic to the virus itself. Thus, variants that are derived from the virus would inherent have the same characteristics. Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use the virus or variants of the virus. One of ordinary skill in the art would have had a reasonable expectation of success for doing so because the variants of NDV would inherently be a potent inducer of interferon in humans and promotes the formation of tumor necrosis factor.

Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

9. Claims 342, 351-353 and 363-364 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cassel et al. in view of Yoshiomi et al. (JP 58-116422)

The claims limit the amount to administer to a particular dosage range.

Cassel et al. does not teach the specific dose range that is instantly claimed.

However, Yoshiomi et al. teaches that the dose to administer depends on various factors, such as the symptom, dispensing route, and body weight.

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to adjust the dose amount. One of ordinary skill in the art at the time the invention was made would have been motivated to adjust the dose amount to optimize the treatment protocol for a specific patient or group of patients. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because dosage adjustment is routine experimentation.

Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

Double Patenting

10. Applicant requests that the provisional obviousness-type double patenting rejections set forth in the previous office action be held in abeyance, pending the determination of allowable subject matter.

11. Claims 332, 337-339, 343, 348, 350 and 355 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 13 and 16-18 of copending Application No. 10/700143.

12. Claims 332-334, 336-340, 343-345, 347-350, 353 and 355 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as

being unpatentable over claims 157-158, 161-166, 173-174, 183-185 and 196-197 of copending Application No.09/958809.

13. Claims 332-334, 336-340, 343-345, 347-349, 353 and 355 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 6-9, 11, 19, 50-52, 63, 116-117, 136 and 138 of copending Application No.10/167652, US PGPUB No. 2003/0165465.

14. Claims 332-334, 336-340, 343-345, 347-349, 353 and 355 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 6-9, 11, 19, 50-52, 63, and 116-117 of copending Application No.10/044,955, US PGPUB No. 20030044384.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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